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HEWRITU
November 8, 2001

PATENT APPLICATION # 34
Attorney's Docket No.: 1855.1017-000 (LK595-10)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones, Walter Newman, Jose Saldanha and Mary M. Bendig		
Application No.:	08/700,737	Group:	1644
Filed:	August 15, 1996	Examiner:	P. Gambel

For: HUMANIZED IMMUNOGLOBULIN REACTIVE WITH α4β7 INTEGRIN

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231
on 11-12-01 (Date) Danielle Gath (Signature)
Danielle D. Gath
Typed or printed name of person signing certificate

DECLARATION OF BARRY COUGHLIN UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Barry Coughlin, of 59 Grasmere Cresent, London, Ontario N6G 4N7, Canada, hereby declare and state that:

COPY

1. I am a barrister at law and solicitor of the Superior Court of Ontario licensed by The Law Society of Upper Canada to practice law in the Province of Ontario.

2. I represented Andrew I. Lazarovits, M.D. from 1991 until his death on January 29, 1999.

3. Dr. Lazarovits maintained records of his professional activities, including records of requests for biological materials in his possession and records of materials that were distributed in response to such requests. Following Dr. Lazarovits' death, his records were given either to me for safe keeping or to his widow.

4. I am familiar with Dr. Lazarovits' method of record keeping and conducted a search of the records that were given to me and those that were given to his widow.

5. In my review of Dr. Lazarovits' records, I found no indication that Dr. Lazarovits distributed samples of the Act-1 hybridoma cell line.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Barry Coughlin LL.B. — Nov. 9/01

Barry Coughlin — Date

COPY

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DECLARATION OF ROBERT B. COLVIN, M.D. UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Robert B. Colvin, M.D., of 31 Lancaster Street, Cambridge, Massachusetts, 02140, hereby declare and state that:

COPY

1. I am Chief of the Department of Pathology at Massachusetts General Hospital and the Benjamin Castleman Professor of Pathology at Harvard Medical School, and I conduct research into the rejection of transplanted organs.

2. Dr. Andrew I. Lazarovits joined my laboratory as a research fellow in October 1982, and worked in my laboratory for about 14 months. The Act-1 hybridoma cell line was produced by Dr. Lazarovits while he was working in my laboratory.

3. Dr. Lazarovits left my laboratory to become the Director of Renal Transplantation at University Hospital, London, Ontario, Canada, and directed a research laboratory at University Hospital. Dr. Lazarovits took a sample of the Act-1 hybridoma cell line to his laboratory at University Hospital in order to continue his research using the Act-1 antibody.

4. Dr. Lazarovits died in January 1999.

5. Dr. Lazarovits and I each had possession of the Act-1 hybridoma cell line and controlled the distribution of the Act-1 hybridoma cell line in our possession from the time he left my laboratory until his death.

6. In 1992, the Act-1 hybridoma cell line was provided to Becton Dickinson Advanced Cellular Biology ("Becton Dickinson") for evaluation of the Act-1 antibody as a potential diagnostic agent. The hybridoma cell line was provided to Becton Dickinson under a Materials Transfer Agreement between The General Hospital Corporation, a not-for-profit corporation doing business as Massachusetts General Hospital, and Becton Dickinson. The Materials Transfer Agreement specified that the Act-1 hybridoma cell line, its progeny, mutants and materials derived therefrom were the property of The

General Hospital Corporation and that the Act-1 hybridoma cell line, its progeny, mutants and materials derived therefrom were not to be transferred, distributed or released to third parties by Becton Dickinson without written consent. No such written consent was requested.

7. Becton Dickinson conducted their evaluation of the Act-1 antibody, concluded that the Act-1 hybridoma cell line and antibody did not suit their commercial purposes, and returned the Act-1 hybridoma cell line to The General Hospital Corporation.

8. In 1995, The General Hospital Corporation and LeukoSite, Inc. entered into a License Agreement under which LeukoSite, Inc. was granted an exclusive license to the Act-1 hybridoma cell line for the purpose of making, having made, using and selling antibody derived from the Act-1 hybridoma cell line and antibody conjugates in the field of use. Subject to the terms of the agreement, a sample of the Act-1 hybridoma cell line was provided to LeukoSite, Inc.

9. Except as set forth in Paragraphs 6-8, samples of the Act-1 hybridoma cell line have not been provided from my laboratory to any others.

10. Dr. Lazarovits and I remained in contact until his death in January 1999. It is my understanding that Dr. Lazarovits did not distribute the Act-1 hybridoma cell line from his laboratory.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Robert B. Colvin, M.D.

11/09/01
Date

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Applicants:	Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones, Walter Newman, Jose Saldanha and Mary M. Bendig		
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Filed:	August 15, 1996	Examiner:	P. Gambel

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on 11.12.01 Danielle Gath
Date Signature

Danielle D. Gath
Typed or printed name of person signing certificate

DECLARATION OF WALTER NEWMAN, Ph.D. UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, Walter Newman, Ph.D., of 3 Durham Street, Apartment 3, Boston, Massachusetts 02115, hereby declare and state that:

1. I was an employee of LeukoSite, Inc., an assignee of the above-referenced patent application, from 1993 until December 1999. I was Director of Research at LeukoSite, Inc. from 1993 until 1997 and then became Senior Vice President, Research, Monoclonal Antibody Discovery and Preclinical Development. Following the merger of LeukoSite, Inc. and Millennium Pharmaceuticals, Inc. in December 1999, I became Senior Vice President, Biotherapeutics, Millennium Pharmaceuticals, Inc. I remained Senior Vice President, Biotherapeutics, Millennium Pharmaceuticals, Inc. until September 2001, when I left the company to pursue other opportunities.

2. I am an inventor of the above-referenced patent application and I am familiar with the application, the invention claimed therein and the Office Action mailed April 4, 2000.

3. In March of 1995, LeukoSite, Inc. entered into a License Agreement with The General Hospital Corporation, a not-for-profit corporation doing business as Massachusetts General Hospital, under which LeukoSite, Inc. was granted an exclusive license to the Act-1 hybridoma cell line for the purpose of making, having made, using and selling antibody derived from the Act-1 hybridoma cell line and antibody conjugates in the field of use. Subject to the terms of the agreement, a sample of the Act-1 hybridoma cell line was provided to LeukoSite, Inc.

4. After LeukoSite, Inc. and The General Hospital Corporation entered into the License Agreement, Dr. Lazarovits forwarded requests for samples of the Act-1 monoclonal antibody or Act-1 hybridoma cell line that he received to me for consideration.

5. In March 1996, I contacted Dr. Lazarovits to confirm whether the Act-1 hybridoma cell line had been distributed to others. Dr. Lazarovits stated that he had not distributed the Act-1 hybridoma cell line.

6. LeukoSite, Inc. did not distribute samples of the Act-1 hybridoma cell line.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Walter Newman

Walter Newman, Ph.D.

1/8/01

Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Paul D. Ponath, Douglas J. Ringler, S. Tarran Jones, Walter Newman, Jose Saldanha and Mary M. Bendig

Application No.: 08/700,737 Group: 1644

Filed: August 15, 1996 Examiner: P. Gambel

For: HUMANIZED IMMUNOGLOBULIN REACTIVE WITH α4β7 INTEGRIN

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Date Signature

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STATEMENT UNDER 37 C.F.R. § 1.806 AND § 1.808

Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. § 1.806 and § 1.808 the undersigned states:

1. The above-referenced application contains reference to a biological deposit. Murine Act-1 Hybridoma cell line, which produces the murine Act-1 monoclonal antibody that binds human α4β7, was deposited under the provisions of the Budapest Treaty on August 22, 2001, on behalf Millennium Pharmaceuticals, Inc., 75 Sidney Street, Cambridge, MA 02139, U.S.A., at the American Type Culture

Collection, 10801 University Boulevard, Manassas, Virginia 20110, U.S.A., under Accession No. PTA-3663.

2. Deposit PTA-3663 will be maintained in a public depository for the enforceable life of the patent which issues from the above-referenced application, a term of at least thirty years from the date of deposit or at least five years after the most recent request for the furnishing of a sample of the deposit is received by the depository, whichever is longer.

3. In accordance with 37 C.F.R. §1.808(a)(1), access to deposit PTA-3663 will be available during the pendency of the above-referenced application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. §1.14 and 35 U.S.C. §122.

4. In accordance with 37 C.F.R. §1.808(a)(2), and except as permitted by 37 C.F.R. §1.808(b), all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on the above-referenced application.

5. The undersigned is an agent of record.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Robert H. Underwood

Robert H. Underwood
Registration No. 45,170
Telephone (978) 341-0036
Facsimile (978) 341-0136

Concord, Massachusetts 01742-9133

Dated: November 12, 2001

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on 11.12.01 Danielle D. Gath
Date Signature

Danielle D. Gath
Typed or printed name of person signing certificate

STATEMENT UNDER 37 C.F.R. § 1.804(b)

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, Walter Newman, Ph.D., of 3 Durham Street, Apartment 3, Boston, Massachusetts 02115, hereby state that:

1. I am a co-inventor of the above-referenced patent application, and I am familiar with the application and the invention claimed therein.

2. The above-referenced application, as amended, contains reference to a biological deposit. Murine ACT-1 Hybridoma cell line, which produces murine ACT-1 monoclonal antibody that binds human $\alpha 4\beta 7$, was deposited under the provisions of the Budapest Treaty on August 22, 2001, on behalf Millennium Pharmaceuticals, Inc., 75 Sidney Street, Cambridge, MA 02139, U.S.A., at the American Type Culture Collection, 10801 University Boulevard, Manassas, Virginia 20110-2209, U.S.A., under Accession No. PTA-3663.

3. The hybridoma cell line deposited at the American Type Culture Colection under Accession No. PTA-3663 is a biological material specifically identified in the subject application as filed.

Walter Newman, Ph.D.

11/8/01

Date

COPY